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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,485	04/21/2006	Huang-Ping Wu	BYD02_010_US	5411

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EXAMINER	
SALZMAN, KOURTNEY R	
ART UNIT	PAPER NUMBER
1724	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,485	WU ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1724	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,14-17,26,30,31,33,45,61,65,68 and 74-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,14-17,26,30,31,33,45,61,65,68 and 74-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2010 has been entered.

2. Claims 1, 30, 45, 61 and 82 are currently amended.

3. Claims 1, 2, 7, 14-17, 26, 30, 31, 33, 45, 61, 65, 68 and 74-85 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 85 seeks a broader range of correlation between the current and concentration than that of the independent claim from with it depends. This is indefinite. Claim 61 seeks patentable protection for a concentration from 0 to 400 mg/dL while claim 85 for a concentration from 0 to 600 mg/dL. Despite the argument previously submitted that the need for a linear relationship at 600

mg/dL makes a more specific claim. This explanation is not sufficient to overcome this rejection, as while it may be more difficult to achieve the level of 600 mg/dL linearly; this is not a relevant explanation as to the scope of the claim. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 7, 15, 26, 30, 31, 45 and 74-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of HODGES et al (US PG PUB 2001/0052470) and TANIIKE et al (US PG PUB 2001/0006149)

Regarding claims 1 and 15, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and a mediator (c. 10, l. 49-52), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. The limitation included in the amendment requiring the reagent pieces to be present "prior to use of the sensor strip in an analysis" carries no patentable weight in light of MPEP section 2144 which states that the manner of use of an apparatus does not distinguish it from the prior art.

Therefore, as the sample is added, the ferricyanide will react invariably forming ferrocyanide, a second soluble redox species. At some point during processing, it would have been obvious for there to be an excess (or more than 1:1 ratio of the first soluble redox species (ferricyanide) to the second redox species (ferrocyanide, produced during the reaction) because if an excess is not present the reaction with the enzyme cannot proceed, causing an inaccurate reading in the sensor itself. The first redox species would be the limiting agent, causing errors in the sensor concentration readings. In the interest of compact prosecution another interpretation is also presented below giving patentable weight to the final limitation of the claim.

WINARTA et al fails to disclose the use of two species of a redox pair placed in the reagent prior to use and explicitly teach the molar ratio of these two redox species. In addition, WINARTA et al isn't explicit in the use of an electroactive organic molecule as the mediator in the first reagent.

HODGES et al teaches a biosensor comprising glucose oxidase and a mediator of ferricyanide in paragraphs 3-7. Moreover, HODGES et al teaches inevitably both species of the mediator are present prior to use of the sensor yet the intended mediator is in a much larger concentration comparatively at the end of paragraph 7.

At the time of the invention, it would have been obvious to one of ordinary skill in the art for both species of the mediator to be present on the electrode, as is disclosed in HODGES et al, on the electrode of WINARTA et al because this occurs after the sensor is assembled naturally, without any other interaction in the cell.

The combination of HODGES et al and WINARTA et al fails to disclose the use of an electroactive organic molecule.

TANIIKE et al discloses the use of either benzoquinone or ferricyanide as the mediator of choice in paragraph 36.

It would have been obvious to one of ordinary skill in the art to utilize the benzoquinone mediator, as in TANIIKE et al, as the mediator in reagent one of WINARTA et al because they would provide equivalent substitutions with the same predictable result of electron transfer for redox equations as they are stated in the paragraph to be equivalents. Moreover, if one did not choose to substitute the benzoquinone mediator of TANIIKE et al for the ferricyanide of WINARTA et al, it would have been obvious to utilize both mediators simultaneously (allowable since the claim is open ended) because TANIIKE et al discloses the use of multiple mediators to be also operable in the sensor.

Regarding claim 2, the composition of the first and second reagent layers is different because, as shown in WINARTA et al, one reagent layer comprises an enzyme while the other does not.

Regarding claims 7, 74 and 75, HODGES et al teaches the ferrocyanide concentration much lower, obviously in excess of 10:1 ratio.

Regarding claims 26 and 78, a third electrode is shown in to be present in figure 2 as W1 or R (whichever is not utilized as the first electrode). The reagent layer present is described in column 10, lines 41-44. The redox species is ferricyanide, as described in the first and second reagent mixes.

Regarding claim 30, Regarding claims 1 and 15, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and a mediator (c. 10, l. 49-52), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. The limitation included in the amendment requiring the reagent pieces to be present "prior to use of the sensor strip in an analysis" carries no patentable weight in light of MPEP section 2144 which states that the manner of use of an apparatus does

not distinguish it from the prior art. Therefore, as the sample is added, the ferricyanide will react invariably forming ferrocyanide, a second soluble redox species. At some point during processing, it would have been obvious for there to be an excess (or more than 1:1 ratio of the first soluble redox species (ferricyanide) to the second redox species (ferrocyanide, produced during the reaction) because if an excess is not present the reaction with the enzyme cannot proceed, causing an inaccurate reading in the sensor itself. The first redox species would be the limiting agent, causing errors in the sensor concentration readings. In the interest of compact prosecution another interpretation is also presented below giving patentable weight to the final limitation of the claim.

WINARTA et al fails to disclose the use of two species of a redox pair placed in the reagent prior to use and explicitly teach the molar ratio of these two redox species. In addition, WINARTA et al isn't explicit in the use of an electroactive organic molecule as the mediator in the first reagent.

HODGES et al teaches a biosensor comprising glucose oxidase and a mediator of ferricyanide in paragraphs 3-7. Moreover, HODGES et al teaches inevitably both species of the mediator are present prior to use of the sensor yet the intended mediator is in a much larger concentration comparatively at the end of paragraph 7.

At the time of the invention, it would have been obvious to one of ordinary skill in the art for both species of the mediator to be present on the electrode, as is disclosed in HODGES et al, on the electrode of WINARTA et al because this occurs after the sensor is assembled naturally, without any other interaction in the cell.

The combination of HODGES et al and WINARTA et al fails to disclose the use of an electroactive organic molecule.

TANIIKE et al discloses the use of either benzoquinone or ferricyanide as the mediator of choice in paragraph 36.

It would have been obvious to one of ordinary skill in the art to utilize the benzoquinone mediator, as in TANIIKE et al, as the mediator in reagent one of WINARTA et al because they would provide equivalent substitutions with the same predictable result of electron transfer for redox equations as they are stated in the paragraph to be equivalents. Moreover, if one did not choose to substitute the benzoquinone mediator of TANIIKE et al for the ferricyanide of WINARTA et al, it would have been obvious to utilize both mediators simultaneously (allowable since the claim is open ended) because TANIIKE et al discloses the use of multiple mediators to be also operable in the sensor.

Regarding claim 31, the composition of the first and second reagent layers is different because, as shown in WINARTA et al, one reagent layer comprises an enzyme while the other does not.

Regarding claim 45, WINARTA et al shows cover 50 to overhang the reagent layers connected to the base on the right hand side. TANIIKE et al also shows the cover 12 to be attached to the base via 10 and 6. The cover of TANIIKE et al also overhangs the reagents.

Regarding claim 76 and 77, since no specific first soluble redox species is required by the claim, it would be obvious to one of ordinary skill in the art for any of the materials listed in the specification as possible first soluble redox species, including the ferricyanide of WINARTA et al, to fulfill this requirement. Furthermore, it is known in the art for the reduction potential of ferricyanide is .436 V well above the reduction potentials required by the instant application.

Regarding claims 79 and 80, WINARTA et al makes it clear the intention of having the enzyme only present in one of the reagent layers and with the combination of TANIIKE et al, the benzoquinones will only be present on the enzyme electrode since the modification identified allows for the substitution of any mediator for any of the others listed with the same functional effect of ionic

transfer. Furthermore, the ferricyanide, with the substitution of benzoquinones on the first reagent, will only be present in the second, as combined in claims 1 and 30.

8. Claims 61, 65, 68 and 81-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of TANIIKE et al (US PG PUB 2001/0006149).

Regarding claims 61 and 85, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and a mediator (c. 10, l. 49-52), a second electrode (W1 or R) and a second reagent layer comprising a first soluble redox species comprising ferricyanide (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. WINARTA et al discloses starting a reading by applying a blood sample to the strip in column 13, line 66-column 14, line 1. WINARTA et al teaches the application of potential, reading the current and correlating to concentrations in column 11, lines 59-66. Moreover, these are standard operating steps for electrochemical gas sensors which obtain readings on concentration. WINARTA et al teaches the final limitation of the claim in example 4 and figure 6 where it is taught that the sensors of WINARTA show a linear relationship between current and concentration from 35 to 1000 mg/dL. (c. 14, l. 25-28)

WINARTA et al is not explicit as to the mediator required to be an electroactive organic molecule in the first reagent.

TANIIKE et al teaches benzoquinone species to be used interchangeably with ferricyanide (as in the first reagent mediator) in paragraph 36.

At the time of the invention, it would have been obvious to utilize an electroactive organic molecule as in TANIIKE et al in lieu of the ferricyanide of WINARTA et al because benzoquinones are disclosed to be just as effective substitutes in performing the redox electron transfer necessary as ferricyanide, as stated by their interchangeability taught in TANIIKE et al (paragraph 36). Moreover, if one did not choose to substitute the benzoquinone mediator of TANIIKE et al for the ferricyanide of WINARTA et al, it would have been obvious to utilize both mediators simultaneously (allowable since the claim is open ended) because TANIIKE et al discloses the use of multiple mediators to be also operable in the sensor.

Regarding claims 65 and 68, the first reagent layer comprises glucose oxidase (c. 10, l. 49-54) and the oxidized (or reducible species) mediator ferricyanide (c. 9, l. 15-18) in WINARTA et al.

Regarding claims 81 and 82, a third electrode is shown in to be present in figure 2 as W1 or R (whichever is not utilized as the first electrode). The reagent layer present is described in column 10, lines 41-44. The redox species is ferricyanide, as described in the first and second reagent mixes. The examples 1 and 2 from column 12 to 13 disclose the use of two different potentials for readings of each set of electrodes.

Regarding claim 83, the first and second layers are different due to the inclusion of the enzyme on the first and no enzyme on the second.

Regarding claim 84, WINARTA et al makes it clear the intention of having the enzyme only present in one of the reagent layers and with the combination of TANIIKE et al, the benzoquinones will only be present on the enzyme electrode. Furthermore, the ferricyanide, with the substitution of benzoquinoes on the first reagent, will only be present in the second, as combined in claim 61.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of HODGES et al (US PG PUB 2001/0052470) and TANIIKE et al (US PG PUB 2001/0006149), as applied to claim 1, in further view of MORRIS et al (Morris, N. A., M. F. Cardosi, B. J. Birch, and A. P. Turner. "An Electrochemical Capillary Fill Device for the Analysis of Glucose Incorporating Glucose oxidase and Ruthenium (III) Hexamine as Mediator." *Electroanalysis* 4.1 (1992): 1-9.).

The combination of WINARTA et al, HODGES et al and TANIIKE et al teaches all the limitations of claim 1, including the use of ferricyanide as the first soluble redox species. The combination of references fails to disclose ruthenium (II) hexamine or ruthenium (III) hexamine as the first soluble redox species.

MORRIS et al teaches a glucose sensor incorporating glucose oxidase with the use of ruthenium (III) hexamine as the mediator of choice in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the ruthenium (III) hexamine mediator, as in MORRIS et al, as the mediator of WINARTA et al, because the use of a positively charged mediator (ruthenium (III) hexamine) improves the kinetics of the reaction over the use of negatively charged mediator such as ferricyanide, as stated by MORRIS et al on page 7. Moreover, it would have been obvious to substitute one known mediator for another known mediator for the same result of electroactivity and electron-transfer.

10. Claims 16, 17 and 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA (US 6,287,451), in view of HODGES et al (US PG PUB 2001/0052470) and TANIIKE et al (US PG PUB 2001/0006149), as applied to claims 1 and 30, in view of BLOCZYNSKI et al (US 5,520,786).

The combination of WINARTA et al, HODGES et al and TANIIKE et al teach all the limitations of claims 1 and 30, as discussed above including the use of

ferricyanide and benzoquinone as the electroactive organic molecule, but fails to detail the use of the materials disclosed in the above stated claims. While glucose oxidase is disclosed in the example, WINARTA et al discloses the use of any enzyme and mediator combination which work together as disclosed in column 8, lines 43-52.

BLOCZYNSKI et al teaches glucose sensor comprising the mediators 3-phenylimino-3H-phenothiazine or 3-phenylimino-3H-phenoxazine in the abstract.

At the time of the invention, it would have been obvious to utilize 3-phenylimino-3H-phenoxazine or 3-phenylimino-3H-phenothiazine, as in BLOCZYNSKI et al, for the ferricyanide mediator of WINARTA et al, because it would have been obvious to substitute one known electron transfer mediator for another. Furthermore, the use of either of the phenothiazine or phenoxazine mediators facilitates electrochemical oxidation at lower potentials than standard mediators, making it more beneficial in regeneration, as stated in column 17, lines 2-17 of BLOCZYNSKI et al.

Response to Arguments

11. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

12. Regarding the 112 rejections of claims for lack of antecedent basis, have been resolved by the amendment and are withdrawn. Regarding the rejection of claim 79, 80

and 84, the explanation given is sufficient to overcome the rejection. Regarding claim 85, this rejection has been maintained as addressed in the rejection above.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
12/15/2010